

Stability Report # 183G03
SU010398 expiring

ACCO. USA
WHEELING, ILLINOIS 60090

15044



0505 15044 1
PEN/VERT FEUILLE/VERDE SUAVE

Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

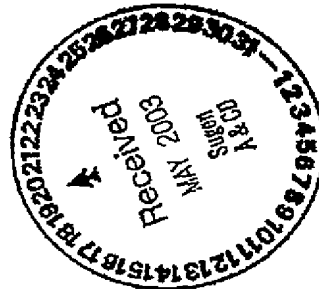
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#00	CAPSULE APPEARANCE	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CAPSULE COLOR	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT APPEARANCE	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT COLOR	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SMELL	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GT01#01_S	(HPLC TITER) SAMPLE#1	97.95	1	%		90.000	- 110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#2	97.96	1	%		90.000	- 110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#3	97.25	1	%		90.000	- 110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE TITER (HPLC)	97.72	1	%		90.000	- 110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	TOTAL CORRELATED SUBSTANCES	0.18	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GSC01#00	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GKF01#00	(HUMIDITY) SAMPLE #1	2.37	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #2	2.4	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #3	2.38	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE HUMIDITY	2.38	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI



Submission Id: 116305
Sample ID (Request No.): 20021134
User sample ID (lot): **183G03**

Sample Type: SU010398 (PNU280940AD) -- CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#01	SAMPLE#1	94.01	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#2	99.04	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#3	100.16	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#4	94.01	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#5	88.41	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#6	94.58	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	DISSOLUTION	95.03	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	STANDARD DEVIATION	4.208	1	std-1				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	C.V.	4.43	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MIN. DISSOLUTION VALUE	88.41	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MAX. DISSOLUTION VALUE	100.16	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI

PHARMACIA

Global Pharmaceutical Sciences - Italy

Analyses Report

Laboratory
Information
Management
System

Submission Id: 116305

Sample ID (Request No.) : 20021134

User sample ID (lot) : 183G03

Sample Type: SUD10398 (PNU280840AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GC02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 15 minutes: 76.5% (C.V.=13.9%)

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Analyses Report

Laboratory
Information
Management
System

Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU280240AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 45 minutes: 99.97% (C.V.=1.16%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS than 0.05%

Total correlated substances: 0.18%



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Analyses Report

Laboratory
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Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): **183G03**

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01400, component: IMPURITIES NOT LESS THAN 0.05%



Submission Id: 116305
Sample ID (Request No.): 20021134

User sample ID (lot): **I83G03**

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

RRT Area (%)

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Analyses Report

Laboratory
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Submission Id: 116305
Sample ID (Request No.): 20021134
User sample ID (lot): **183G03**
Sample Type: SU010398 (PNU280940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01H00, component: IMPURITIES NOT LESS THAN 0.05%



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Analyses Report

Laboratory
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Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method

083GSC01400, component: IMPURITIES NOT LESS THAN 0.05%

0.66 0.12



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Analyses Report

Laboratory
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Submission Id: 116305	Request Type: STABILITY	Condition :
Sample ID (Request No.): 20021134	Stability Study: I83G03	APPROVED
User sample ID (lot): I83G03	Pack Type: 30 ml PLASTIC BOTTLE	Status :
Sample Type: SU010398 (PNU280940AD) CAPSULE	Storage Condition: 25°C/60% U.R.	COMPLETE
	Time Label: 6 MONTHS	
	Preparation purpose: CLINICAL SUPPLY + STABILITY	

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.91 0.08

Analyses Report

Submission Id: 116305
Sample ID (Request No.): 20021134
User sample ID (lot): 183G03
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%
1.00 99.82 (SU11248)

SUBMISSION APPROVED BY Volker ECK
APPROVE DATE 15-may-2003

SAMPLE APPROVED BY: ROSARIA MARIANI
APPROVE DATE: 17-may-2002

Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

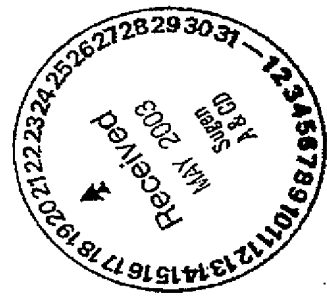
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#00	CAPSULE APPEARANCE	0=UNCHANGED	1	td				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CAPSULE COLOR	0=UNCHANGED	1	td				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT APPEARANCE	0=UNCHANGED	1	td				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT COLOR	0=UNCHANGED	1	td				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SMELL	0=UNCHANGED	1	td				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GT01#01_S	(HPLC TITER) SAMPLE#1	97.43	1	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#2	98.55	1	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#3	97.23	1	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE TITER (HPLC)	97.74	1	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	TOTAL CORRELATED SUBSTANCES	0.21	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GSC01#00	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #1	2.77	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #2	2.9	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #3	2.8	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE HUMIDITY	2.82	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI



Condition :
APPROVED
Status :
COMPLETE

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Submission Id: 116307
Sample ID (Request No.) : 20021136
User sample ID (lot) : I83G03
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Venier
083GDS01#01	SAMPLE#1	96.29	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#2	95.75	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#3	95.82	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#4	100.05	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#5	99.51	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#6	97.90	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	DISSOLUTION	97.72	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	STANDARD DEVIATION	1.755	1	std-1				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	C.V.	1.8	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MIN. DISSOLUTION VALUE	95.75	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MAX. DISSOLUTION VALUE	100.05	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI

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Analyses Report

Laboratory
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Submission Id: 116307

Sample ID (Request No.) : 20021136

User sample ID (lot) : 1B3G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 1B3G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method 083GCC02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 15 minutes: 96.74% (C.V. = 1.77%)

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Analyses Report

Laboratory
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Submission Id: 116307

Sample ID (Request No.): 20021136

User sample ID (lot): **I83G03**

Sample Type: SU010398 (PNU280840AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 45 minutes: 97.72% (C.V.: 1.86%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.21%

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Analyses Report

Laboratory
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Submission Id: 116307

Sample ID (Request No.): 20021136

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%



Submission Id: 116307

Sample ID (Request No.): 20021136

User sample ID (lot): 183G03

Sample Type: SU010388 (PNU290840AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

RRT	Area (%)



Submission Id: 116307

Sample ID (Request No.): 20021136

User sample ID (lot): I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method

083GSC01#00, component IMPURITIES NOT LESS THAN 0.05%

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Analyses Report

Laboratory
Information
Management
System

Submission Id: 115307

Sample ID (Request No.): 20021136

User sample ID (lot): I83G03

Sample Type: SU010398 (PNU280940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.86

0.08

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Global Pharmaceutical Sciences - Italy

Analyses Report

Laboratory
Information
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Submission Id: 116307

Sample ID (Request No.): 20021136

User sample ID (lot): 183G03

Sample Type: SUD10398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.91 0.06



Analyses Report

Condition :
APPROVED
Status :
COMPLETE

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): I83G03
Sample Type: SU010388 (PNU280940AD) CAPSULE
25MG

Samples Notes:

Observations on the Method 083GGSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.84 0.07



Analyses Report

Submission Id: 116307	Request Type: STABILITY	Condition : APPROVED
Sample ID (Request No.): 20021136	Stability Study: I83G03	Status : COMPLETE
User sample ID (lot): I83G03	Pack Type: 30 ml PLASTIC BOTTLE	
Sample Type: SU010398 (PNU290940AD) CAPSULE	Storage Condition: 40°C/75% U.R.	
25MG	Time Label: 6 MONTHS	
	Preparation, purpose: CLINICAL SUPPLY + STABILITY	

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

1.00 99.79 (SU11248)

SUBMISSION APPROVED BY Volker ECK
APPROVE DATE 15-may-2003

SAMPLE APPROVED BY: ROSARIA MARIANI
APPROVE DATE: 17-may-2002



Analyses Report

Laboratory
Information
Management
System

Global Pharmaceutical Sciences - Italy

Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

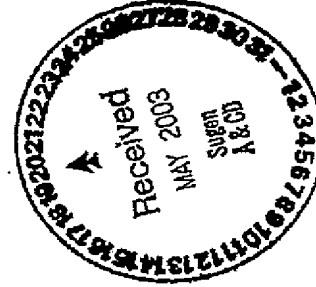
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#00	CAPSULE APPEARANCE	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
	CAPSULE COLOR	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
	CONTENT APPEARANCE	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
	CONTENT COLOR	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
	SMELL	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
083GT01#01_S	(HPLC TITER) SAMPLE#1	97.48	1	%		90.000	- 110.000	15545/33 AUG2002	CAPPUCCIO	FINETTI
	(HPLC TITER) SAMPLE#2	96.12	1	%		90.000	- 110.000	15545/33 AUG2002	CAPPUCCIO	FINETTI
	(HPLC TITER) SAMPLE#3	97.03	1	%		90.000	- 110.000	15545/33 AUG2002	CAPPUCCIO	FINETTI
	AVERAGE TITER (HPLC)	96.88	1	%		90.000	- 110.000	15545/33 AUG2002	CAPPUCCIO	FINETTI
	TOTAL CORRELATED SUBSTANCES	0.32	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
083GSC01#00	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
083GKF01#00	(HUMIDITY) SAMPLE #1	2.07	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #2	2.1	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #3	2.2	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
	AVERAGE HUMIDITY	2.12	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI





Analyses Report

Submission Id: 116953
Sample ID (Request No.): 20022083
User sample ID (lot): 183G03

Sample Type: SUD10398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 9 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED

Status:
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#01	SAMPLE#1	89.91	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#2	88.29	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#3	96.41	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#4	96.41	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#5	91.00	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#6	91.00	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	DISSOLUTION	92.17	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	STANDARD DEVIATION	3.431	1	std-1				1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	C.V.	3.72	1	%				1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	MIN. DISSOLUTION VALUE	88.29	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	MAX. DISSOLUTION VALUE	96.41	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI

Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU200940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule

PHARMACIA



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Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

containing yellow-orange powder

Observations on the Method 083GSDS01#01, component: DISSOLUTION

Average dissolution at 15 minutes: 74.93% (interval 63.91%-83.97%)

PHARMACIA



Global Pharmaceutical Sciences - Italy

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Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GDS01#01, component: DISSOLUTION

Average dissolution at 45 minutes: 96.56% (interval 95.33%-98.04%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.32%

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Submission Id: 116953
Sample ID (Request No.): 20022083
User sample ID (lot) 183G03

Sample Type: SU010398 (PNU280940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Submission Id: 116953
Sample ID (Request No.): 20022083
User sample ID (lot) **I83G03**
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 9 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition : **APPROVED**
Status : **COMPLETE**

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

RRT	AREA%
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Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): **I83G03**

Sample Type: **SUJ010398 (PNU290940AD) CAPSULE**
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.66

0.11

Submission Id: 116953
Sample ID (Request No.): 20022083
User sample ID (lot) **I83G03**
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 9 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.94 0.05

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Analyses Report

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Submission Id: 118953

Sample ID (Request No.) 20022083

User sample ID (lot) 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

1.00 99.88 (SU11248)



Analyses Report

Submission Id: 116953
Sample ID (Request No.): 20022083
User sample ID (lot) **I83G03**

Sample Type: SU010398 (PNU/290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

1.06 0.18

SUBMISSION APPROVED BY Volker ECK
APPROVE DATE 15-may-2003

SAMPLE APPROVED BY: GIORGIO FINETTI
APPROVE DATE: 03-sep-2002

PHARMACIA

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Submission Id: 117497
Sample ID (Request No.): 20022972
User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

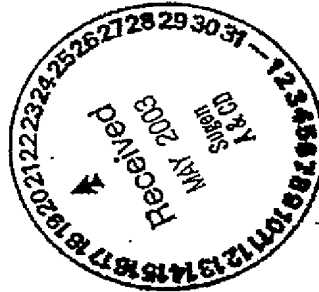
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#00	CAPSULE APPEARANCE	0=UNCHANGED	1	bt				1554559- NOV 2002	CAPPUCCIO	MACCARI
	CAPSULE COLOR	0=UNCHANGED	1	bt				1554559- NOV 2002	CAPPUCCIO	MACCARI
	CONTENT APPEARANCE	0=UNCHANGED	1	bt				1554559- NOV 2002	CAPPUCCIO	MACCARI
	CONTENT COLOR	0=UNCHANGED	1	bt				1554559- NOV 2002	CAPPUCCIO	MACCARI
	SMELL	0=UNCHANGED	1	bt				1554559- NOV 2002	CAPPUCCIO	MACCARI
083GT01#01_S	(HPLC TITER) SAMPLE#1	95.84	1	%		90.000	110.000	1554559- NOV 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#2	96.17	1	%		90.000	110.000	1554559- NOV 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#3	97.03	1	%		90.000	110.000	1554559- NOV 2002	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	96.35	1	%		90.000	110.000	1554559- NOV 2002	CAPPUCCIO	MACCARI
	TOTAL CORRELATED SUBSTANCES	0.15	1	%				1554559- NOV 2002	CAPPUCCIO	MACCARI
083GSC01#00	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	1	%				1554559- NOV 2002	CAPPUCCIO	MACCARI
083GKF01#00	(HUMIDITY) SAMPLE #1	2.1	1	%				1554559- NOV 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #2	2.2	1	%				1554559- NOV 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #3	2.1	1	%				1554559- NOV 2002	CAPPUCCIO	MACCARI
	AVERAGE HUMIDITY	2.13	1	%				1554559- NOV 2002	CAPPUCCIO	MACCARI



svfbolla.rdf

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GIUSEPPE MACCARI

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Analyses Report

Submission Id: 117497

Sample ID (Request No.): 20022872

User sample ID (lot): I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE

25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#01	SAMPLE#1	88.22	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#2	93.41	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#3	101.19	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#4	97.04	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#5	94.97	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#6	92.89	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	DISSOLUTION	94.62	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	STANDARD DEVIATION	4.349	1	std-1				15545/59- NOV 2002	CAPPUCCIO	MACCARI
	C.V.	4.6	1	%				15545/59- NOV 2002	CAPPUCCIO	MACCARI
	MIN. DISSOLUTION VALUE	88.22	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	MAX. DISSOLUTION VALUE	101.19	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI

Submission Id: 117497
Sample ID (Request No.): 20022972
User sample ID (lot): [83G03]

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GMC01#01 TOTAL AEROBIC BACTERIA	J	IN LIMITS	1	bt		ABSENT		15545/59- NOV 2002	CAPPUCCIO	MACCARI
						IN LIMITS				
						NOT DETECTABLE				
						NOT PLANNED				
ESCHERICHIA COLI		ABSENT	1	bt		ABSENT		15545/59- NOV 2002	CAPPUCCIO	MACCARI
						NOT DETECTABLE				
						NOT PLANNED				
SALMONELLA		ABSENT	1	bt		ABSENT		15545/59- NOV 2002	CAPPUCCIO	MACCARI
						NOT DETECTABLE				
						NOT PLANNED				
FUNGI		IN LIMITS	1	bt		ABSENT		15545/59- NOV 2002	CAPPUCCIO	MACCARI
						IN LIMITS				
						NOT DETECTABLE				
						NOT PLANNED				
STAPHYLOCOCCUS AUREUS		ABSENT	1	bt		ABSENT		15545/59- NOV 2002	CAPPUCCIO	MACCARI
						NOT DETECTABLE				
						NOT PLANNED				
ENTEROBACTERIA		IN LIMITS	1	bt		ABSENT		15545/59- NOV 2002	CAPPUCCIO	MACCARI
						IN LIMITS				
						NOT DETECTABLE				



Analyses Report

Submission Id: 117497
Sample ID (Request No.): 20022972
User sample ID (lot): 183G03
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 12 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GMC01#01	ENTEROBACTERIA	IN LIMITS	1	bx				NOT PLANNED		



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Submission Id: 117497
Sample ID (Request No.): 20022972
User sample ID (lot): **I83G503**

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/80% U.R.

Time Label: 12 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Average dissolution at 15 minutes: 77.24% (C.V.: 7.27%)

Submission Id: 117497
Sample ID (Request No.): 20022972
User sample ID (lot): **183G03**
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 12 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Observations on the Method 083GDS01#01, component: DISSOLUTION
Average dissolution 45 minutes: 97.39% (C.V.: 2.25%)

Observations on the Method 083GMC01#01, component: TOTAL AEROBIC BACTERIA
Total bacterial count < 10 Ufc/g (Report num. 02.16971)

Observations on the Method 083GMC01#01, component: ENTEROBACTERIA
Enterobacteria < 10 Ufc/g (Report num. 02.16971)

Observations on the Method 083GMC01#01, component: ESCHERICHIA COLI
Report num. 02.16971

Observations on the Method 083GMC01#01, component: FUNGI
Fungi (Yeasts + Molds) < 10 Ufc/g (Report num. 02.16971)

Observations on the Method 083GMC01#01, component: SALMONELLA
Report num. 02.16971

Observations on the Method 083GMC01#01, component: STAPHYLOCOCCUS AUREUS
Report num. 02.16971

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%
Total correlated substances: 0.15%

PHARMACIA



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Submission Id: 117497
Sample ID (Request No.): 20022972

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/80% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method 083GSC01400, component: IMPURITIES NOT LESS
THAN 0.05%

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Submission Id: 117497

Sample ID (Request No.): 20022972

User sample ID (lot) **183G03**

Sample Type: **SU010398 (PNU280940AD)** CAPSULE
25MG

Request Type: **STABILITY**

Stability Study: **183G03**

Pack Type: **30 ml PLASTIC BOTTLE**

Storage Condition: **25°C/60% U.R.**

Time Label: **12 MONTHS**

Preparation purpose: **CLINICAL SUPPLY + STABILITY**

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GC01#00, component: IMPURITIES NOT LESS
THAN 0.05%

RRT

Area (%)

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Submission Id: 117497

Sample ID (Request No.): 20022972

User sample ID (lot): 183G03

Sample Type: SUD10398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method 083GC01#00, component: IMPURITIES NOT LESS
THAN 0.05%

Submission Id: 117497

Sample ID (Request No.): 20022972

User sample ID (lot) **I83G03**

Sample Type: **SUO10398 (PNU290940AD) CAPSULE**
25MG

Request Type: **STABILITY**

Stability Study: **I83G03**

Pack Type: **30 ml PLASTIC BOTTLE**

Storage Condition: **25°C/60% U.R.**

Time Label: **12 MONTHS**

Preparation purpose: **CLINICAL SUPPLY + STABILITY**

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method 983GC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.65 0.10



Submission Id: 117497

Sample ID (Request No.): 20022972

User sample ID (lot) I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method

083GC01#00, component: IMPURITIES NOT LESS
THAN 0.05%

0.94

0.05

Submission Id: 117497

Sample ID (Request No.): 20022972

User sample ID (lot): **183G03**

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method 083GC01#00, component: IMPURITIES NOT LESS THAN 0.05%

1.00 99.85 (SU 11248)

SUBMISSION APPROVED BY Volker ECK
APPROVE DATE 15-may-2003

SAMPLE APPROVED BY: GIUSEPPE MACCARI
APPROVE DATE: 27-nov-2002

Time Points



Integrated Analytical Bulletin

Pharmaceutical Development

Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): 183G03

Sample Date : 18/07/2002

Sample Type: SUD10398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

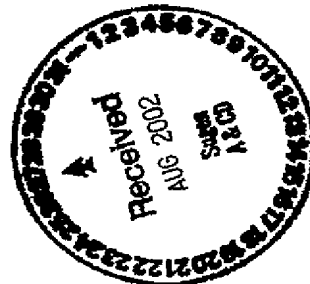
Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCC002#D 0	CAPSULE APPEARANCE	0=UNCHANGED	0					15545/32 AUG2002	CAPPUCCIO	FINETTI
	CAPSULE COLOR	0=UNCHANGED	0					15545/32 AUG2002	CAPPUCCIO	FINETTI
	CONTENT APPEARANCE	0=UNCHANGED	0					15545/32 AUG2002	CAPPUCCIO	FINETTI
	CONTENT COLOR	0=UNCHANGED	0					15545/32 AUG2002	CAPPUCCIO	FINETTI
	SMELL	0=UNCHANGED	0					15545/32 AUG2002	CAPPUCCIO	FINETTI
083GT01#01 _S	(HPLC TITER) SAMPLE#1	97.48	%			90.000	- 110.000	15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HPLC TITER) SAMPLE#2	96.12	%			90.000	- 110.000	15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HPLC TITER) SAMPLE#3	97.03	%			90.000	- 110.000	15545/32 AUG2002	CAPPUCCIO	FINETTI
	AVERAGE TITER (HPLC)	96.88	%			90.000	- 110.000	15545/32 AUG2002	CAPPUCCIO	FINETTI
	TOTAL CORRELATED SUBSTANCES	0.32	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
083GSC01#0 0	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #1	2.07	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #2	2.1	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #3	2.2	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
	AVERAGE HUMIDITY	2.12	%					15545/32 AUG2002	CAPPUCCIO	FINETTI





Pharmaceutical Development

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Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): 183G03

Sample Date: 18/07/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date: 17/09/2001

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#0 1	SAMPLE#1	89.91		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#2	88.29		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#3	96.41		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#4	96.41		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#5	91.00		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#6	91.00		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	DISSOLUTION	92.17		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	STANDARD DEVIATION	3.431		std-1				15545/32 AUG2002	CAPPUCCIO	FINETTI
	C.V.	3.72		%				15545/32 AUG2002	CAPPUCCIO	FINETTI
	MIN. DISSOLUTION VALUE	88.29		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	MAX. DISSOLUTION VALUE	96.41		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI



Integrated Analytical Bulletin

Pharmaceutical Development

Submission Id: 116953
Sample ID (Request No.): 20022083
User sample ID (lot): 183G03
Sample date: 18/07/2002
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nerviano

Batch Manufacture Date: 17/09/2001
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 9 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**
Status: **COMPLETE**

Samples Notes:

Observations on the Method 083GCC02#00, component: CAPSULE APPEARANCE
Opaque brick red colored, format 3, hard gelatin capsule containing red-orange powder
Observations on the Method 083GDS01#01, component: DISSOLUTION
Average dissolution at 15 minutes: 74.93% (interval 63.91%-89.37%)
Average dissolution at 45 minutes: 96.59% (interval 95.33%-98.04%)
Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS
THAN 0.05%

Total correlated substances: 0.32%

RRT	AREA%
0.66	0.11
0.94	0.05
1.00	99.68 (SU1248)
1.06	0.16

Approved by: FINETTI
Approval date: 05-aug-2002



Integrated Analytical Bulletin

Pharmaceutical Development

Submission id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): 183G03

Sample Date : 18/04/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Batch Manufacture Date : 17/09/2001

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

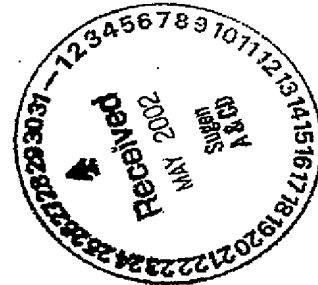
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCC02#0	CAPSULE APPEARANCE	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CAPSULE COLOR	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT APPEARANCE	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT COLOR	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SMELL	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GTI01#01 -S	(HPLC TITER) SAMPLE#1	97.95	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#2	97.96	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#3	97.25	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE TITER (HPLC)	97.72	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GSC01#0	TOTAL CORRELATED SUBSTANCES	0.18	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GKF01#00	(HUMIDITY) SAMPLE #1	2.37	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #2	2.4	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #3	2.36	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE HUMIDITY	2.36	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI



PHARMACIA

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Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (Int): 183G03

Sample Date : 18/04/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#0 1	SAMPLE#1	94.01	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#2	99.04	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#3	100.16	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#4	94.01	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#5	88.41	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#6	94.56	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	DISSOLUTION	95.03	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	STANDARD DEVIATION	4.208	std-1				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	C.V.	4.43	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MIN. DISSOLUTION VALUE	88.41	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MAX. DISSOLUTION VALUE	100.16	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI

Submission Id: 116305
Sample ID (Request No.): 20021134
User sample ID (lot) 183G03

Sample Date : 18/04/2002
Sample Type: SU010398 (PNU280940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001
Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Observations on the Method 083GCO2#00, component: CAPSULE APPEARANCE
Opaque brick red colored, format 3, hard gelatin capsule containing red-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION
Dissolution at 15 minutes: 76.5 % (C.V. = 13.9%)
Dissolution at 45 minutes: 99.97% (C.V. = 1.16%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS
THAN 0.05%

Total correlated substances: 0.18%

RRT	Area (%)
0.66	0.12
0.91	0.06
1.00	99.82 (SU11248)

Condition :
APPROVED
Status :
COMPLETE

Batch Manufacture Date : 17/09/2001
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Approved by: MARIANI
Approval date: 17-may-2002

Submission Id: 116307

Sample ID (Request No.): 20021136

User sample ID (lot): 183G03

Sample Date : 18/04/2002

Sample Type: SU010398 (PNU2B0840AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Condition :
APPROVED
Status :
COMPLETE

Batch Manufacture Date : 17/09/2001

Stability Study: 183G03

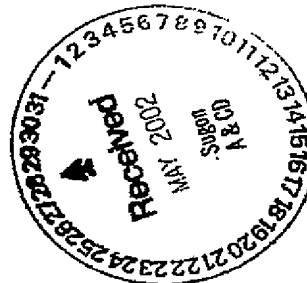
Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCC02#0	CAPSULE APPEARANCE	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CAPSULE COLOR	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT APPEARANCE	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT COLOR	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SMELL	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GT01#01	(HPLC TITER) SAMPLE#1	97.43	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#2	98.55	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#3	97.23	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE TITER (HPLC)	97.74	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GSC01#0	TOTAL CORRELATED SUBSTANCES	0.21	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GKF01#00	(HUMIDITY) SAMPLE #1	2.77	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #2	2.9	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #3	2.8	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE HUMIDITY	2.82	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI



Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): **183G03**
Sample Date: 18/04/2002
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nerviano

Batch Manufacture Date: 17/09/2001
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**
Status: **COMPLETE**

Samples Notes:

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#0 1	SAMPLE#1	96.29	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#2	95.75	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#3	96.82	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#4	100.05	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#5	99.51	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#6	97.90	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	DISSOLUTION	97.72	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	STANDARD DEVIATION	1.755	std-1				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	C.V.	1.8	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MIN. DISSOLUTION VALUE	96.75	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MAX. DISSOLUTION VALUE	100.05	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI



Pharmaceutical Development

Submission Id: 116307
 Sample ID (Request No.): 20021136
 User sample ID (lot): **183G03**
 Sample Date : 18/04/2002
 Sample Type: SU010398 (PNU290940AD) CAPSULE
 25MG
 Batch Manufacture Date : 17/09/2001
 Stability Study: 183G03
 Pack Type: 30 ml PLASTIC BOTTLE
 Storage Condition: 40°C/75% U.R.
 Time Label: 6 MONTHS
 Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
 Status :
COMPLETE

Stability Study Start Date : 18/10/2001
 Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing red-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 15 minutes: 96.74% (C.V. = 1.77%)

Dissolution at 45 minutes: 97.72% (C.V. = 1.86%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.21%

RRT	Area (%)
0.66	0.08
0.91	0.06
0.94	0.07
1.00	99.79 (SU11248)

Approved by: MARIANI
 Approval date: 17-may-2002

Submission Id: 115471

Sample ID (Request No.): 20020185

User sample ID (ict): 183G03

Sample Date : 18/01/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#0 0	CAPSULE APPEARANCE	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CAPSULE COLOR	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CONTENT APPEARANCE	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CONTENT COLOR	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	SMELL	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GTI01#01 _S	(HPLC TITER) SAMPLE#1	96.84	%		90.000	110.000	143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#2	96.31	%		90.000	110.000	143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#3	96.41	%		90.000	110.000	143/44- JAN 2002	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	97.19	%		90.000	110.000	143/44- JAN 2002	CAPPUCCIO	MACCARI
	TOTAL CORRELATED SUBSTANCES	0.21	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GSC01#0 0	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #1	1.9	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GKF01#00	(HUMIDITY) SAMPLE #2	1.82	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #3	1.9	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	AVERAGE HUMIDITY	1.87	%				143/44- JAN 2002	CAPPUCCIO	MACCARI

Submission Id: 115471

Sample ID (Request No.): 20020165

User sample ID (lot): **183G03**

Sample Date: 18/01/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date: 17/09/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#0 1	SAMPLE#1	101.14	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#2	106.48	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#3	109.97	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#4	106.90	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#5	105.33	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#6	104.08	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	DISSOLUTION	105.65	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	STANDARD DEVIATION	2.96	std-1				143/44- JAN 2002	CAPPUCCIO	MACCARI
	C.V.	2.8	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	MIN. DISSOLUTION VALUE	101.14	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	MAX. DISSOLUTION VALUE	109.97	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI

Submission Id: 115471

Sample ID (Request No.): 20020165

User sample ID (lot): 183G03

Sample Date : 18/01/2002

Sample Type: SUJ010398 (PNU230940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Batch Manufacture Date : 17/09/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status:
COMPLETE

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.21%

RRT	Area (%)
1.00	99.79 (SU 11248)
1.97	0.09
2.06	0.12

Approved by: MACCARI
Approval date: 04-feb-2002

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Submission Id: 115473

Sample ID (Request No.): 20020167

User sample ID (lot): 183G03

Sample Date : 18/01/2002

Sample Type: SU010398 (PNU290940AD)CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/08/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#0	CAPSULE APPEARANCE	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CAPSULE COLOR	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CONTENT APPEARANCE	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CONTENT COLOR	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	SMELL	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GT01#01 _S	(HPLC TITER) SAMPLE#1	99.21	%		90.000	110.000	143/44-JAN 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#2	96.18	%		90.000	110.000	143/44-JAN 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#3	95.82	%		90.000	110.000	143/44-JAN 2002	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	97.07	%		90.000	110.000	143/44-JAN 2002	CAPPUCCIO	MACCARI
	TOTAL CORRELATED SUBSTANCES	0.41	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GSC01#0	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #1	1.8	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GKF01#00	(HUMIDITY) SAMPLE #2	1.7	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #3	1.9	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	AVERAGE HUMIDITY	1.8	%				143/44- JAN 2002	CAPPUCCIO	MACCARI



Pharmaceutical Development

Integrated Analytical Bulletin

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Submission Id: 115473

Sample ID (Request No.): 20020167

User sample ID (lot): 183G03

Sample Date : 18/01/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01H0 1	SAMPLE#1	101.47	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#2	102.93	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#3	104.56	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#4	106.96	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#5	101.34	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#6	98.51	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	DISSOLUTION	102.63	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	STANDARD DEVIATION	2.917	std-1				143/44- JAN 2002	CAPPUCCIO	MACCARI
	C.V.	2.84	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	MIN. DISSOLUTION VALUE	98.51	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	MAX. DISSOLUTION VALUE	106.96	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI



Submission Id: 115473
Sample ID (Request No.): 20020167
User sample ID (lot): 183G03
Sample Date: 18/01/2002
Sample Type: SU010398 (PNU290940AD) CAPSULE 25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nerviano
Samples Notes:

Batch Manufacture Date: 17/09/2001
Request Type: RELEASE
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.
Time Label: 3 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: APPROVED
Status: COMPLETE

Observations on the Method 083GCC02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.41%

RRT	Area (%)
0.94	0.05
1.00	99.60 (SU 11248)
1.97	0.07
2.06	0.29

Approved by: MACCARI
 Approval date: 04-feb-2002



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Submission ID: 115029
Sample ID (Request No.): 20013360
User sample ID (lot): 183G403
Sample Date: 18/11/2001
Sample Type: SL010308 (7N1L2501040) CAPSULE
25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PO/Pharmacia Nordino
Samples Notes:

Batch Manufacture Date: 17/09/2001
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Conditions: 25°C/60% UR.
Time Label: 1 MONTH
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**
Status: **COMPLETE**

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
013GSC00240 0	CAPSULE APPEARANCE	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	CAPSULE COLOR	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	CONTENT APPEARANCE	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	CONTENT COLOR	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	SMELL	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
013GTF01401 S	(HPLC TITER) SAMPLE#1	98.763	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	(HPLC TITER) SAMPLE#2	98.218	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	(HPLC TITER) SAMPLE#3	95.918	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	AVERAGE TITER (HPLC)	96.3	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
013GSC01400 0	TOTAL CORRELATED SUBSTANCES	0.306	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	IMPURITIES NOT LESS THAN 0.05% SEE TEXT		%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
013GKE01400	(HUMIDITY) SAMPLE #1	1.8	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	(HUMIDITY) SAMPLE #2	1.6	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	(HUMIDITY) SAMPLE #3	1.7	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	AVERAGE HUMIDITY	1.7	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	



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Submission No: 115029

Sample ID (Request No.): 20013300

User sample ID (lot): K3G013

Sample Date: 18/11/2001

Sample Type: SU010308 (PNL2810040D) CAPSULE

25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: PDCPharmacia Nordiano

Samples Notes:

Batch Manufacture Date: 17/06/2001

Stability Study: 003503

Pack Type: 30 ml PLASTIC BOTTLE

Storage Conditions: 25°C/60% U.R.

Time Label: 1 MONTH

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
003G0150190 1	(SAMPLE #1)	98.2	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #2)	81.8	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #3)	92.4	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #4)	88.0	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #5)	89.0	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #6)	94.7	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(DISSOLUTION)	90.35	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(STANDARD DEVIATION)	5.25	sd-1				14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(C.V.)	5.81	%				14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(MINIMUM DISSOLUTION VALUE)	81.8	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(MAXIMUM DISSOLUTION VALUE)	98.24	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI

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Condition: **APPROVED**

Status: **COMPLETE**

Batch Manufacture Date: 17/03/2001

Stability Study: 03G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 1 MONTH

Preparation purpose: CLINICAL SUPPLY + STABILITY

Submission No: 115029

Sample ID (Request No.): 200103100

User sample ID (lot): 03G03

Sample Date: 18/11/2001

Sample Type: SU010088 (FNU20004045) CAPSULE
25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: FOPPharmacia Novartis

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Brick red colored capsule containing yellow-orange powder

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.306%

RRT	Area %
0.06	0.090
1.00	99.90 (SU 11245)
2.15	0.076
2.17	0.140

Approved by: MACCARI
Approval date: 30-JAN-2001



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Submission ID: 115031
Sample ID (Request No.): 20010302
User sample ID (lot): 183G03
Sample Date: 18/11/2001
Sample Type: 8U010888 (PNU12009040) CAPSULE
25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PDPharmacia Nordano

Batch Manufacture Date: 17/09/2001
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% UR
Time Label: 1 MONTH
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED
Status:
COMPLETE

Samples Notes:

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
003G001000	CAPSULE APPEARANCE	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
0	CAPSULE COLOR	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	CONTENT APPEARANCE	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	CONTENT COLOR	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	SMELL	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
003G010100	(HPLC TITER) SAMPLE #1	97.43	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
S	(HPLC TITER) SAMPLE #2	89.03	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	(HPLC TITER) SAMPLE #3	95.23	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	AVERAGE TITER (HPLC)	97.25	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
003G030100	TOTAL CORRELATED SUBSTANCES	0.15	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
0	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
003G040100	(HUMIDITY) SAMPLE #1	1.8	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	(HUMIDITY) SAMPLE #2	1.9	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	(HUMIDITY) SAMPLE #3	1.8	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	AVERAGE HUMIDITY	1.83	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	



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Submission Id: 113031
Sample ID (Request No.): 20013302
User sample ID (lot): 1839003
Sample Date: 18/11/2001
Sample Type: SUG 10308 (FNU1230040AD) CAPSULE
20MG
Stability Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PDPharmacia Nordisk

Batch Manufacture Date: 17/08/2001
Stability Study: 181803
Pack Type: 30 ml PLASTIC BOTTLE
Storage Conditions: 40°C/75% UR.
Time Label: 1 MONTH
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**
Status: **COMPLETE**

Samples Notes:

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data	Analyses	Analyst	Verifier
0833DS01#0 1	SAMPLE #1	94.7	%		80.000		143/20 NOV 2001		CAPPUCCHIO	MACCARI
	SAMPLE #2	99.3	%		80.000		143/20 NOV 2001		CAPPUCCHIO	MACCARI
	SAMPLE #3	95.2	%		80.000		143/20 NOV 2001		CAPPUCCHIO	MACCARI
	SAMPLE #4	87.5	%		80.000		143/20 NOV 2001		CAPPUCCHIO	MACCARI
	SAMPLE #5	97.9	%		80.000		143/20 NOV 2001		CAPPUCCHIO	MACCARI
	SAMPLE #6	97.3	%		80.000		143/20 NOV 2001		CAPPUCCHIO	MACCARI
DISSOLUTION		95.3	%		80.000		143/20 NOV 2001		CAPPUCCHIO	MACCARI
STANDARD DEVIATION		4.182	std				143/20 NOV 2001		CAPPUCCHIO	MACCARI
C.V.		4.39	%				143/20 NOV 2001		CAPPUCCHIO	MACCARI
MINIMUM DISSOLUTION VALUE		87.5	%		80.000		143/20 NOV 2001		CAPPUCCHIO	MACCARI
MAXIMUM DISSOLUTION VALUE		99.33	%		80.000		143/20 NOV 2001		CAPPUCCHIO	MACCARI



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Reference ID: 119031

Sample ID (Request No.): 20013302

User sample ID (lot): 853G03

Sample Date: 18/11/2001

Sample Type: SJ010305 (PUL2300040)CAPSULE
25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: PDPharmacia Nemo

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Brick red colored capsule containing yellow-orange powder

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.145%

PKT	Area %
0.66	0.45
1.00	90.65 (SU-11248)
2.17	0.49

Batch Manufacture Date: 17/06/2001

Stability Study: 853G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Conditions: 40°C/75% U.R.

Test Label: 1 MONTH

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Approved by: MACCARI
Approval date: 30-Jan-2001



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Submission Id: 11406

Sample ID (Request No.): 2001S150

User sample ID (lot): B23303

Sample Date: 01/11/2001

Sample Type: SU010350 (PMU2500-40AD) CAPSULE

25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: POXPharmacia Nordino

Batch Manufacture Date: 17/08/2001

Stability Study: B23303

Pack Type: BULK

Storage Conditions: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED

Status:
COMPLETE

Samples Notes: Opaque brick red colored capsule in containing yellow-orange powder

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
0030C001M0 1	APPEARANCE	COMPLIANT	td				14301 OCT 2001	CAPPUCCIO	MACCARI
0030C001M01	HPLC IDENTIFICATION	POSITIVE	td				14301 OCT 2001	CAPPUCCIO	MACCARI
0030G101M01 _R	(HPLC TITER) SAMPLE#1	97.31	%		95.000	105.000	14301 OCT 2001	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#2	98.10	%		95.000	105.000	14301 OCT 2001	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#3	98.67	%		95.000	105.000	14301 OCT 2001	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	98.09	%		95.000	105.000	14301 OCT 2001	CAPPUCCIO	MACCARI
0030S001M0 D	TOTAL CORRELATED SUBSTANCES	0.273	%				14301 OCT 2001	CAPPUCCIO	MACCARI
	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				14301 OCT 2001	CAPPUCCIO	MACCARI
0030KF01M00	(HUMIDITY) SAMPLE #1	1.85	%				14301 OCT 2001	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #2	1.78	%				14301 OCT 2001	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #3	1.98	%				14301 OCT 2001	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE	1.9	%				14301 OCT 2001	CAPPUCCIO	MACCARI



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Submission ID: 114806

Sample ID (Request No.): 20013158

User sample ID (lot): 183G03

Sample Date: 01/1/2001

Sample Type: SU010358 (P1120081042) CAPSULE

25MG

Batch Manufacture Date: 17/02/2001

Stability Study: 183G03

Pack Type: BULK

Storage Condition: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED

Status:
COMPLETE

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: PO Pharmacia Malaysia

Samples Notes: Opaque brick red colored capsule in containing yellow-orange powder

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS0140 1_12	SAMPLE #1	85.23	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #2	92.79	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #3	98.54	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #4	93.86	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #5	81.52	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #6	84.74	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #7	89.32	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #8	95.91	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #9	90.51	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #10	105.5	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #11	90.31	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #12	83.12	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	DISSOLUTION	92.82	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	STANDARD DEVIATION	7.031	sd-1				14301 OCT 2001	CAPPUCCIO	MAGCARI
	C.V.	7.59	%				14301 OCT 2001	CAPPUCCIO	MAGCARI
	MINIMUM DISSOLUTION VALUE	81.62	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	MAXIMUM DISSOLUTION VALUE	105.5	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI



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Submission ID: 114908

Sample ID (Request No.): 20013158

User sample ID (lot): 853603

Sample Date: 01/12/2001

Sample Type: SL010098 (PNU230040AD)

CAPSULE

25MG

Stability Study Start Date: 18/10/2001

Stability Product Number: 2001017 - Manufacturer: PD/Pharmacia Nordino

Samples Notes: Opaque brick red colored capsule in containing yellow-orange powder

Batch Manufacture Date: 17/09/2001

Sublot Study: 853603

Pack Type: BULK

Storage Conditions: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED

Status:
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
0856MCC140 1	TOTAL AEROBIC BACTERIA	IN LIMITS	td				14/01 OCT 2001	CAPPUCCHIO	MACCARI
	ESCHERICHIA COLI	ABSENT	td				14/01 OCT 2001	CAPPUCCHIO	MACCARI
	SALMONELLA	ABSENT	td				14/01 OCT 2001	CAPPUCCHIO	MACCARI
	FUNGI	IN LIMITS	td				14/01 OCT 2001	CAPPUCCHIO	MACCARI
	STAPHYLOCOCCUS AUREUS	ABSENT	td				14/01 OCT 2001	CAPPUCCHIO	MACCARI
	ENTEROBACTERIA	IN LIMITS	td				14/01 OCT 2001	CAPPUCCHIO	MACCARI



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Submission ID: 114806

Sample ID (Request No.): 20013156

User sample ID (Lot): 183G03

Sample Date: 01/11/2001

Sample Type: SUB10306 (PRLD200940AD)

CAPSULE

25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: FOFPharmacia Merck

Samples Notes: Opaque brick red colored capsule in containing yellow-orange powder

Batch Manufacture Date: 17/08/2001

Stability Study: 183G03

Pack Type: BULK

Storage Condition: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED

Status:
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
0030UC0140	CONTENT UNIFORMITY#1	98.588	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
1	CONTENT UNIFORMITY#2	98.280	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#3	98.928	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#4	97.354	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#5	100.192	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#6	100.479	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#7	101.103	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#8	98.637	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#9	98.947	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#10	100.852	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY	99.54	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	STANDARD DEVIATION	1.192	sd-1				143/01 OCT 2001	CAPPUCCO	MACCARI
	C.V.	1.2	%				143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY MAX	101.183	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY MIN	97.384	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI



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Submission ID: 114908

Sample ID (Request No.): 20013158

User sample ID (lot): 183G03

Sample Name: D17122001

Sample Type: SLD 18388 (PNU230941AD) CAPSULE
250(G)

Stability Study Start Date: 18/02/2001

Stability Protocol Number: 2001017 - Manufacturer: PDMPHarmacia Novartis

Samples Notes: Opaque brick red colored capsule containing yellow-orange powder

Batch Manufacturing Date: 17/09/2001

Stability Study: 183G03

Pack Type: BULK

Storage Condition: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Observations on the Method 083GDS01#_12, component: DISSOLUTION

Dissolution after 15 minutes equal to: 66% (min. 35%-max. 88.7%)

Dissolution after 30 minutes equal to: 92.6% (min. 31.5%-max. 105.6%)

Dissolution after 45 minutes equal to: 97.5% (min. 88%-max. 101.9%)

Observations on the Method 083GMC01#01, component: TOTAL AEROBIC BACTERIA

Total bacterial count < 20 Ufc/g

Observations on the Method 083GMC01#01, component: ENTEROBACTERIA

Enterobacteria < 10 Ufc/g

Observations on the Method 083GMC01#01, component: FUNGI

Fungi (Yeast + Molds) < 10 Ufc/g

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.273%

RRT Area %

0.58 0.064

0.91 0.062

1.00 90.727 (SU 11240)

1.06 0.107

2.19 0.060

Observations on the Method

083GTC18#01_IR, component: (HPLC TITER)
SAMPLE #3



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Submission ID: 114805

Sample ID (Request No.): 20073168

User sample ID (lot): 853503

Sample Date: 01/11/2001

Sample Type: SUB10395 (PIN12309(040)) CAPSULE
25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufactures: PDPharmacia Nordano

Batch Manufacture Date: 17/02/2001

Stability Study: 83308

Pack Type: BULK

Storage Conditions: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Samples Notes: Opaque brick red colored capsule containing yellow-orange powder

Observations on the Method 083GTC18#01_IR, component: (HPLC TITER) SAMPLE#3

Observations on the Method 083GTC18#01_IR, component: AVERAGE TITER (HPLC)

Average titer determined based on nine different samples

Approved by: MACCARI
Approval date: 28-Nov-2001